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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,838	01/31/2002	Alfred E. Mann	PD-0294 DIV	6151

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MEDTRONIC MINIMED INC.
18000 DEVONSHIRE STREET
NORTHRIDGE, CA 91325-1219

EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/062,838

Applicant(s)

MANN ET AL.

Examin r

Ann Y. Lam

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-95 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 56-95 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: ____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed August 13, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. (Examiner does not have a copy of the documents listed under "Other Documents" in the IDS submitted.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 84-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 84 appears to claim an infusion system as well as a method. (Examiner will prosecute claims 84-95 as though they are claiming a method.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Worthington et al., 5,822,715.

As to claim 56, 65 and 84, Worthington et al. discloses an infusion device including a processor, see column 17, line 34, a bolus estimator (10) that utilizes externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body; see column 6, lines 62-66, column 7, lines 43-46, and column 18, lines 13-21, and a programmer, the programmer including: a processor (22) to process data for a bolus estimator; a housing (12) to contain the processor; a display (14 or 16) including at least one touch screen element; at least one button to interface with the processor and the bolus estimator; at least one audio indication device (54); and at least one portable power supply (e.g., power supply that provides power to processor 22); wherein the externally supplied values for the bolus estimator are input into the programmer using either the at least one button or at least one touch screen element to estimate the amount of fluid to be infused.

As to claims 57 and 75, the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value, see column 6, lines 62-66, column 8, lines 31-35, and column 18, lines 13-21.

As to claims 58, 66, 67 and 76, the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus, see for example, column 5, lines 53-56, and column 17, lines 47-58.

As to claims 59, 60, 62, 63, 68, 69, 77 and 78, the liquid to be infused is insulin, and the material to be ingested is carbohydrates,

As to claims 61, 70 and 80, the bolus estimator is considered to include a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. An on/off button for example is considered a lockout as claimed.

As to claims 64, 71-73, and 81-83, a duration factor and codes as claimed are disclosed, see column 8, lines 34-35, and column 7, lines 43-67.

As to claim 74, also disclosed are an interfacing means (22, 24, 14), an inputting means (16), and calculating means (22) as claimed.

As to claim 79, an infusing means is disclosed at column 17, lines 31-34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

Claims 84-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al., 5,822,715, in view of Welch et al., 5,319,363.

Worthington et al. discloses the invention substantially as claimed, see above, except for a touchscreen.

Welch et al. discloses a touchscreen as a means for interacting with a processor, see column 7, line 12. It would have been obvious to provide a touchscreen in the Worthington et al. device, as taught by Welch et al., as a known means for interacting with a processor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
February 23, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700